510(K) SUMMARY
FOR
SYNGO.CT BONE READING

MAR 1 2 2013

Submitted by:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: February 26, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

Mrs. Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 448-1772 Fax: (610) 448-1778
Email: kimberly.mangum@siemens.com

2. **Device Name and Classification**

| | |
|---|---|
| **Product Name:** | syngo.CT Bone Reading |
| **Propriety Trade Name:** | syngo.CT Bone Reading |
| **Classification Name:** | Computed Tomography X-ray System |
| **Classification Panel:** | Radiology |
| **CFR Section:** | 21 CFR §892.1750 |
| **Device Class:** | Class II |
| **Product Code:** | 90JAK |

## 3. Substantial Equivalence:

Siemens syngo.CT Bone Reading post processing software package is substantially equivalent to the following medical devices in commercial distribution:

| *Predicate Device Name* | *FDA Clearance Number* | *FDA Clearance Date* |
|---|---|---|
| Siemens syngo.CT Vascular Analysis | K112020 | 08/18/2011 |
| Siemens syngo Multimodality Workplace | K072728 | 04/22/2008 |
| Siemens SOMATOM Definition Edge | K120579 | 05/23/2012 |

## 4. Device Description:

syngo.CT Bone Reading is image analysis software for CT volume data sets which has been continuously acquired with computed tomography (CT) imaging systems.

syngo.CT Bone Reading combines basic and advanced digital image processing and visualization tools for easy manual identification, marking and reporting of pathologies such as bone lesions or fractures.

The software combines following digital image processing and visualization tools:

- multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)
- geometric measurement tools (distance line, polyline, marker, arrow, angle)
- HU measurement tools (Pixel lens, ROI circle, ROI polygonal, ROI freehand, VOI sphere)
- curved MPR visualization (unfolded ribs and spine views), cross-section MPRs
- tools for creation and editing of anatomical centerline paths
- tools for creation and editing of anatomical labels

Reporting and documentation of results is facilitated by using of appropriate reporting tool, statistics and creation of ranges and snapshots.

Thereby, the user is always free to decide when or whether to apply particular tools. Accordingly, the user can operate the application in basic

reading mode only and use conventional navigation on 2D and 3D views. Furthermore, during the whole reading process, the reading clinician has full control on the reported measurements, text and images.
In the following sections we list all tools and explain in detail how different tools are operated, and which steps are to be followed in order to complete and report a clinical diagnosis.

## 5. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

syngo.CT Bone Reading software package is designed to be operated on syngo.via VA20 platform in a single or multi user environment.

syngo.CT Bone Reading software package provides similar evaluation, reporting, and visualization tools and functionality as the predicate devices syngo MultiModality Workplace (K072728, clearance date April 22, 2008) and syngo.CT Vascular Analysis (K112020, clearance date August 18, 2011). syngo MultiModality Workplace contains visualization tools such as Curved Mode (in 3D application), Panoramic, and Paraxial Views.

These tools can be used to generate reformatted MPR images which are equivalent to the curved and cross-section MPRs in syngo.CT Bone Reading. Predicate device syngo.CT Vascular Analysis also has equivalent visualization tools. Predicate device SOMATOM Definition Edge (K120579, clearance date May 23, 2012) includes similar image processing and visualization tools such as curved MPRs for ribs and spine as well as suggested labeling of ribs and spine.

syngo.CT Bone Reading has similar indications for use and technological characteristics when compared to the predicate devices; therefore Siemens believes that syngo.CT Bone Reading is substantially equivalent to the predicate devices.

## 6. Nonclinical Testing:

syngo.CT Bone Reading is designed to fulfill the requirements of following standards:

- IEC 60601-1-6 : 2006; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical devices - Application of risk management to medical devices
- DICOM (Digital Imaging and Communications in Medicine) Standard: 2008 DICOM conformity is fully covered by syngo.via implementations.

Non clinical tests were conducted for syngo.CT Bone reading software package during product development. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

**7. Indications for Use:**

The *syngo*.CT Bone Reading is image analysis software for CT volume data sets which has been continuously acquired with computed tomography (CT) imaging systems. The software combines following digital image processing and visualization tools:

- multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)
- geometric measurement tools (distance line, polyline, marker, arrow, angle)
- HU measurement tools (Pixel lens, ROI circle, ROI polygonal, ROI freehand, VOI sphere)
- curved MPR visualization (unfolded ribs and spine views), cross-section MPRs
- tools for creation and editing of anatomical centerline paths
- tools for creation and editing of anatomical labels

The specific visualizations of spine and rib structures allow for easy manual identification and marking of pathologies such as bone lesions or fractures.

Reporting and documentation of results is facilitated by using of appropriate reporting tool, statistics and creation of ranges and snapshots

**8. General Safety and Effectiveness Concerns**:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

**9. Conclusion as to Substantial Equivalence**

In summary, Siemens is of the opinion that the syngo.CT Bone Reading software package does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2013

Siemens Medical Solutions, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
51 Valley Stream Parkway D-02
MALVERN PA 19355

Re: K123584
Trade/Device Name: Syngo.CT Bone Reading
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 8, 2013
Received: February 15, 2013

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

# Indications for Use

510(k) Number (if known): K123584

Device Name: ***syngo.CT Bone Reading***

**Indications for Use:**

The *syngo*.CT Bone Reading is image analysis software for CT volume data sets which has been continuously acquired with computed tomography (CT) imaging systems. The software combines following digital image processing and visualization tools:

- multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)
- geometric measurement tools (distance line, polyline, marker, arrow, angle)
- HU measurement tools (Pixel lens, ROI circle, ROI polygonal, ROI freehand, VOI sphere)
- curved MPR visualization (unfolded ribs and spine views), cross-section MPRs
- tools for creation and editing of anatomical centerline paths
- tools for creation and editing of anatomical labels

The specific visualizations of spine and rib structures allow for easy manual identification and marking of pathologies such as bone lesions or fractures. Reporting and documentation of results is facilitated by using of appropriate reporting tool, statistics and creation of ranges and snapshots.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health
510(k) K123584